Dkt. 43966-CA-PCT-US/JPW/SHS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Graham P. Allaway, et al.
Serial No.	:	Not Yet Known (continuation of U.S. Serial No 08/973,601, filed March 16, 1998)
Filed	:	October 5, 1999
For	:	METHODS FOR USING RESONANCE ENERGY TRANSFER-BASED ASSAY OF HIV-1 ENVELOPE GLYCOPROTEIN-MEDIATED MEMBRANE FUSION, AND KITS FOR PRACTICING SAME

1185 Avenue of the Americas
New York, New York 10036
October 5, 1999

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Please amend the subject application as follows:

In the specification:

On page 1, line 6, after the words "This application is a" and before the words "continuation-in-part" please insert the following words: --continuation of United States Serial No. 08/973,601, filed March 16, 1998, which is a national stage application, filed under 35 U.S.C. §371 of PCT/US96/09894, filed June 7, 1996, which is a--.

On page 1, line 7, before the words "Serial No." and after the words "filed June 7" please delete "08/175,515," and insert the following --08/475,515,--.

In the claims:

Please cancel claims 1-6 without prejudice to applicants' right to pursue the subject matter of these claims in a later-filed application and add the following new claims:

--7. (New) An agent determined to be capable of specifically inhibiting the fusion of a macrophage-tropic primary isolate of HIV-1 to a $CD4^+$ cell, but not a T cell-tropic isolate of HIV-1 to a $CD4^+$ cell, using a method which comprises:

(a) contacting (i) a first appropriate $CD4^+$ cell, which is labeled with a first dye, with (ii) a cell expressing the HIV-1 envelope glycoprotein of the macrophage-tropic primary isolate of HIV-1 on its surface, which is labeled with a second dye, in the presence of an excess of the agent under conditions which would normally permit the fusion of the $CD4^+$ cell to the cell expressing the HIV-1 envelope glycoprotein on its surface in the absence of the agent, the first and second dyes being selected so as to allow resonance energy transfer between the dyes;

(b) exposing the product of step (a) to conditions which would result in resonance energy transfer if fusion has occurred; and

(c) determining whether there is a reduction of resonance energy transfer, when compared with the resonance energy transfer in the absence of the agent;

(d) contacting (i) a second appropriate $CD4^+$ cell, which is labeled with a first dye, with (ii) a cell expressing the HIV-1 envelope glycoprotein of a T cell-tropic isolate of HIV-1 on its surface, which is labeled with a second dye, in the presence of an excess of the agent under conditions which would normally permit the fusion of the $CD4^+$ cell to the cell expressing the HIV-1 envelope glycoprotein on its surface in the absence of the agent, the first and second dyes being selected so as to allow resonance energy

transfer between the dyes;

(e) exposing the product of step (d) to conditions which would result in resonance energy transfer if fusion has occurred; and

(f) determining whether there is a reduction of resonance energy transfer, when compared with the resonance energy transfer in the absence of the agent, wherein a decrease in transfer in step (c) but not step (f) indicates that the agent is capable of specifically inhibiting fusion of the macrophage-tropic primary isolate of HIV-1 to $CD4^-$ cells and a decrease in transfer in step (f) but not step (c) indicates that the agent is capable of specifically inhibiting the fusion of a macrophage-tropic primary isolate of HIV-1 to the $CD4^+$ cells.--

--8. (New) The agent of claim 7, wherein the agent is an antibody.--

--9. (New) An agent capable of specifically inhibiting the fusion of a macrophage tropic primary isolate of HIV-1 with a CD+ cell susceptible to infection by a macrophage-tropic primary isolate of HIV-1.--

--10. (New) A method of inhibiting fusion of a macrophage-tropic primary isolate of HIV-1 with a CD+ cell susceptible to infection by a macrophage-tropic primary isolate of HIV-1 which comprises contacting the $CD4^+$ cell with an amount of an agent capable of specifically inhibiting such fusion so as to thereby inhibit such fusion.--

--11. (New) An agent determined to be capable of specifically inhibiting the fusion of a T cell-tropic isolate

of HIV-1 to a CD4$^-$ cell, but not a macrophage-tropic primary isolate of HIV-1 to a CD4+ cell, using a method which comprises:

(a) contacting (i) a first appropriate CD4$^+$ cell, which is labeled with a first dye, with (ii) a cell expressing the HIV-1 envelope glycoprotein of the macrophage-tropic primary isolate of HIV-1 on its surface, which is labeled with a second dye, in the presence of an excess of the agent under conditions which would normally permit the fusion of the CD4$^+$ cell to the cell expressing the HIV-1 envelope glycoprotein on its surface in the absence of the agent, the first and second dyes being selected so as to allow resonance energy transfer between the dyes;

(b) exposing the product of step (a) to conditions which would result in resonance energy transfer if fusion has occurred; and

(c) determining whether there is a reduction of resonance energy transfer, when compared with the resonance energy transfer in the absence of the agent;

(d) contacting (i) a second appropriate CD4$^+$ cell, which is labeled with a first dye, with (ii) a cell expressing the HIV-1 envelope glycoprotein of a T cell-tropic isolate of HIV-1 on its surface, which is labeled with a second dye, in the presence of an excess of the agent under conditions which would normally permit the fusion of the CD4$^+$ cell to the cell expressing the HIV-1 envelope glycoprotein on its surface in the absence of the agent, the first and second dyes being selected so as to allow resonance energy transfer between the dyes;

(e) exposing the product of step (d) to conditions

which would result in resonance energy transfer if fusion has occurred; and

(f) determining whether there is a reduction of resonance energy transfer, when compared with the resonance energy transfer in the absence of the agent, wherein a decrease in transfer in step (c) but not step (f) indicates that the agent is capable of specifically inhibiting fusion of the macrophage-tropic primary isolate of HIV-1 to $CD4^+$ cells and a decrease in transfer in step (f) but not step (c) indicates that the agent is capable of specifically inhibiting the fusion of a T cell-tropic isolate of HIV-1 to the $CD4^+$ cells.--

--12. (New) The agent of claim 11, wherein the agent is an antibody.--

--13. (New) An agent capable of specifically inhibiting the fusion of a T cell-tropic isolate of HIV-1 with a $CD4^+$ cell susceptible to infection by a T cell-tropic isolate of HIV-1.--

--14. (New) A method of inhibiting fusion of a T cell-tropic isolate of HIV-1 with a $CD4^+$ cell susceptible to infection by a T cell-tropic isolate of HIV-1 which comprises contacting the $CD4^+$ cell with an amount of an agent capable of specifically inhibiting such fusion so as to thereby inhibit such fusion.--

In the Abstract:

Please add page 67 containing the abstract of the disclosure, a copy of which is attached hereto as **Exhibit A**.

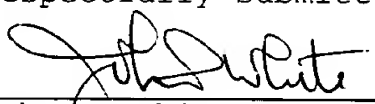
Remarks

Claims 1-6 were pending in the subject application. Applicants have hereinabove canceled claims 1-6 without prejudice to their right to pursue the subject matter of these claims in a later-filed application. Applicants have hereinabove added new claims 7-14. Support for new claims 7-14 may be found inter alia in the specification as follows: claim 7: page 11, lines 28-29 and pages 61-64; claim 8: page 26, line 54; claims 9-10: page 20, lines 28-31; claim 11: page 11, lines 28-29, pages 61-64; claim 12: page 26, line 54; and claim 13-14: page 20, lines 28-31. Accordingly, claims 7-14 involve no issue of new matter and entry of this amendment is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, in addition to the enclosed filing fee of $497.00, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/412,284	10/05/99	1648	$497.00	43966-CA-PCT	5	8	6

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Applicant(s) GRAHAM P. ALLAWAY, MORETON MERSEYSIDE, ENGLAND; VIRGINIA M. LITWIN, FAYETTEVILLE, NY; PAUL J. MADDON, ELMSFORD, NY.

CONTINUING DATA AS CLAIMED BY APPLICANT-
THIS APPLN IS A CON OF 08/973,601 03/16/98
WHICH IS A CIP OF 08/475,515 06/07/95 ABN

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 10/25/99 ** SMALL ENTITY **
TITLE
FLUORESCENCE RESONANCE ENERGY TRANSFER SCREENING ASSAY FOR THE IDENTIFICATION OF HIV-1 ENVELOPE GLYCOPROTEIN-MEDICATED CELL

PRELIMINARY CLASS: 435

DATA ENTRY BY: DURHAM, DESHAWN TEAM: 06 DATE: 10/25/99

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